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REMARKS

Restriction Requirement

The previous election without traverse is affirmed.

Amendment to the Specification

The amendment to the specification corrects an obvious error.

Status of the Claims

The claims remaining in this application are claims 1, 3-8, 10-12, 15-41, 43, 44, 46-69. Claims 1, 3-8, 10-12, 15-38 and 69 are drawn to the elected invention.

The amendments to the claims are supported in the original claims and at paragraphs [0034] and [0048]. No new matter has been added.

Claims 39-41, 43, 44, 46-48 have been amended to change their form from "use" claims to "method" claims. No change in claim scope is intended or effected.

With respect to claims 39-41, 43, 44, 46-48, it is noted that where Applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Rejection under 35 USC § 102—Cox

Claims 1-5 and 35 have been rejected under 35 U.S.C. 102(e) as being anticipated by Cox US 2003/0023190. This rejection and its supporting remarks are respectfully traversed.

Cox does not disclose even the concept of controlling MRI detectability by varying the amount of crosslinking of the hydrogel polymer coating. See *Ex parte Rubin*, 5 U.S.P.Q.2d 1461(BPAI 1987).

The examiner has asserted that the present claims would be inherent in the referenced disclosure. There is, however, no evidence or clear explanation to support the

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examiner's assertion. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990). A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one. *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993), *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

The rejection was unsustainable with regard to the original claims and is even more clearly unsustainable with regard to the amended claims.

Reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of Cox are therefore requested.

Rejection under 35 USC § 102—Bergheim

Claims 1-4 have been rejected under 35 U.S.C. 102(e) as being anticipated by Bergheim et al. US 2004/0249333 (Bergheim). This rejection and its supporting remarks respectfully traversed.

The arguments set forth above with regard to Cox are relevant to Bergheim, the subject matter of which is even more remote from the presently claimed device. For example, Bergheim does not appear to even mention magnetic resonance imaging, much less the concept of cross-linking a hydrogel polymer to a degree sufficient to render a medical device visible under the same.

Reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of Bergheim are therefore requested.

Rejection under 35 USC § 102—DiCosmo

Claims 1-5, 9, 30 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by DiCosmo et al. US 6,475,516 (DiCosmo). This rejection and its supporting remarks are respectfully traversed.

The DiCosmo device is used to deliver drugs from a hydrogel. As with Bergman above, DiCosmo does not appear to even mention magnetic resonance imaging, much less the concept of cross-linking a hydrogel polymer to a degree sufficient to render a medical device visible under the same.

Moreover, as above, there is absolutely no reason to believe the properties of the devices here claimed would be inherent in the reference.

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Reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of DiCosmo are therefore requested.

Rejection under 35 USC § 102—Whitbourne

Claims 1-7, 9, 30 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne US 5,331,027. This rejection and its supporting remarks are respectfully traversed.

Whitbourne discloses "lubricious" coatings. Here again, magnetic resonance imaging is not disclosed, much less so the concept of the present claims. Moreover, there is no support for a holding of inherency.

Reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of Whitbourne are therefore requested.

Rejection under 35 USC § 102—Rosenbluth

Claims 1-8 and 30-32 have been rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbluth et al. US 5,336,208 (Rosenbluth). This rejection and its supporting remarks are respectfully traversed.

Being directed to urinary incontinence pad, the subject matter of Rosenbluth is further removed from the here-claimed invention than any reference discussed so far, and the foregoing comments are even more clearly applicable here.

Reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of Rosenbluth are therefore requested.

Rejection under 35 USC § 102—Weissleder

Claims 1-5, 9-11, 13-22, 28-31 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder et al. US 5,514,379 (Weissleder). This rejection and its supporting remarks are respectfully traversed.

For imaging visibility, Weissleder discloses loading the hydrogel with diagnostic labels, such as a gadolinium containing compound. See Weissleder Abstract and col. 4, lines 1-8. Weissleder discloses crosslinking, but only to ensure insolubility of the hydrogel disclosed. See, e.g., col. 6, lines 33-39. The concept of controlling or

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modifying the degree of visibility to MRI by varying the degree of crosslinking is not disclosed. See *Ex parte Rubin, supra*. The importance of this limitation is illustrated in paragraphs [0034] and [0040] and in Example 6.

Because each and every element of the here-claimed invention is not disclosed in Weissleder reference, the reference clearly fails as an anticipation. See MPEP 2131 and the cases cited therein.

It is possible that the Examiner may be focusing on col. 6, lines 33-39 of Weissleder in which it is state that "[t]hese hydrogels include a polymeric backbone insolubilized by cross-linking agents which allow the hydrogels to absorb large amounts of water, which makes them well suited for proton relaxation imaging, e.g., MRI." In this regard, it well known that paramagnetic materials, e.g., paramagnetic ions such as gadolinium ions, require the proximity of water or another proton-bearing substance, in order to provide enhanced contrast under MRI. See, e.g., the background section of the present specification, including, paragraph [0009]. This concept is, of course, remote from the present invention, in which the degree of visibility to MRI is controlled by varying the degree of crosslinking.

For at least the above reasons, reconsideration and withdrawal of the claim rejection under 35 USC § 102 in view of Weissleder are requested.

Rejection under 35 USC § 103—Weissleder and Michaels

Claims 6-8 have been rejected under 35 U.S.C. 103(b) as being unpatentable over Weissleder in view of Michaels US 6,112,908. This rejection and its supporting remarks are respectfully traversed.

For example, the defects in Weissleder as a reference have been discussed above. Glycerin is taught by Michaels only as a plasticizer, not as a proton source for MRI imaging. Thus the combination of Michaels with Weissleder can in no way remedy those defects.

Reconsideration and withdrawal of the claim rejection under 35 USC § 103 over Weissleder in view of Michaels are therefore requested.

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Rejection under 35 USC § 103—Weissleder and Klaveness

Claim 12 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Klaveness et al. US 6,610,269 (Klaveness). This rejection is respectfully traversed.

Klaveness is cited for its disclosure of starch-coated iron oxide particles. This rejection fails, however, because of the inadequate nature of Weissleder as a reference as discussed above and because Klaveness does not remedy those inadequacies.

Reconsideration and withdrawal of the claim rejection under 35 USC § 103 over Weissleder in view of Klaveness are therefore requested.

Rejection under 35 USC § 103—Weissleder and Peng

Claim 23 has been rejected under 35 U. S. C. 103(a) as being unpatentable over Weissleder in view of Peng et al. US 2002/0061871 (Peng). This rejection and its supporting remarks are respectfully traversed.

This rejection is inadequate because of the defects in Weissleder as a reference (described above) and because Peng does not remedy those defects.

Moreover, Peng deals with pharmaceutical compositions and not with medical devices or MRI. With no motivation or suggestion in the references to take a chelating compound from Peng and incorporate it into Weissleder involves the use of undue hindsight guided only by the instant disclosure. See *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992) and the cases cited therein, as well as MPEP 2142, second paragraph, and the cases cited therein. In particular, see *Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Reconsideration and withdrawal of the claim rejection under 35 USC § 103 over Weissleder in view of Peng are therefore requested.

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Rejection under 35 USC § 103—Weissleder and Cleary

Claims 24-27, 32 and 33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Cleary et al. US 2003/0170308 (Cleary). This rejection and its supporting remarks are respectfully traversed.

For example, Weissleder is deficient as a reference for the reasons discussed above, and Cleary does not make up for those deficiencies.

Moreover, Cleary is relied on for the specific polymers of acrylic acid and acrylamide. Those polymers are used in a completely different environment from Weissleder and the instant claims. It should be noted that all of the polymers disclosed as useful by Weissleder appear to be naturally occurring or slightly modified naturally occurring polymers. There is no disclosure of anything like polymers or copolymers of acrylic acid and acrylamide. Thus, the disclosure of Weissleder actually teaches away from the use of those polymers and copolymers. *In re Baird*, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994). One of ordinary skill in the relevant art would not have a reasonable expectation of success for the substitution of polymers suggested by the examiner. MPEP 2143.02 and the cases cited therein.

Reconsideration and withdrawal of the claim rejection under 35 USC § 103 over Weissleder in view of Cleary are therefore requested.

Rejection under 35 USC § 103—Weissleder

Claims 34, and 36-38 have been rejected under 36 U.S.C. 103(a) as being unpatentable over Weissleder. This rejection and its supporting remarks are respectfully traversed.

This rejection, as did the rejection for anticipation, relies on an assertion of inherency supported only by unfounded speculation. That issue has been discussed at length above. In this rejection the examiner has relied also on statements of obviousness with no supporting authority. Applicant challenges what is in effect taking official notice of the relevant facts. See MPEP 2144.03.

Reconsideration and withdrawal of the claim rejection under 35 USC § 103 over Weissleder are therefore requested.

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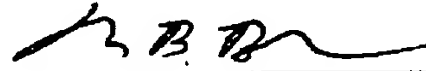
In light of the foregoing amendments and remarks, it is believed that all of the rejections of record have been obviated. Allowance of this application is therefore respectfully requested.

FEES

While it is not believed that any fees are due as a result of this Amendment, the Examiner is authorized to charge any fees that may be due to the undersigned attorney's PTO Deposit Account #50-1047.

Respectfully submitted,

By:



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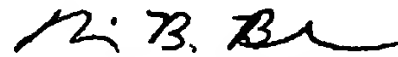
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this document, and any document referenced herein, has been transmitted via facsimile to the US Patent and Trademark Office at (703) 872-9306 on May 2, 2005.

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